VALIDATION RESULTS FOR METHOD NO. Covance Harrogate 2001-042-D2

		MEAN	RELATIVE STD. DEV.(%)	RANGE	SEE (conc)	
ANALYTE	Cotinine					
MATRIX	Human urine					
DATE	10-Aug-01					
LLOQ	(Polynomial regression)	1.0 ng/mL. Accuracy 110.0%. RSD 13.0%				
STANDARD ERROR OF ESTIMATE OF QC SAMPLES (concentration units)						
(SEE = S.D./SQRT (# of determinations))						
	2 ng/mL	Low QC			0.092	
	400 ng/mL	Med QC			6.717	
	750 ng/mL	High QC			6.191	
DESCRIPTIVE INFORMATION ON INSTRUMENT RESPONSE						
Function (Linear, Quatradtic, etc.)	Linear					
Slope (mean)	0.0525					
Intercept (mean)	0.0063					
Other (mean regression value)	0.9972(1/x weighted)					
RECOVERY (as a %)						
High QC in (matrix)=	750 ng/mL					
Med QC in (matrix)=	400 ng/mL					
Low QC in (matrix)=	2 ng/mL					
Results with different sample amounts (results of QC evaluations) intra-assay						
LLOQ QC=	1 ng/mL	1.10	13.0%	0.93-1.30	0.058	
Low QC=	2 ng/mL	2.03	5.8%	1.85-2.06	0.048	
Med QC=	400 ng/mL	382.85	5.6%	354.95-412.42	8.745	
High QC=	750 ng/mL	673.12	1.7%	661.81-686.90	4.639	
Results with different sample amounts (results of QC evaluations) inter-assay						
LLOQ QC=	n/a	n/a	n/a	n/a	n/a	
Low QC=	2 ng/mL	2.07	10.9%	1.71-2.60	0.092	
Med QC=	400 ng/mL	369.71	4.5%	348.61-412.42	6.717	
High QC=	750 ng/mL	673.68	2.3%	649.32-703.56	6.191	
STABILITY (assuming any degradation is linear):						
a) Room Temperature in Matrix (+/- %/24 hrs)		5.8% maximum				
b) Freeze/thaw (+/-% /3 cycles)		-0.5% maximum				
c) Injector (+/- %/24 hrs)	Refrigerated 68 hrs	2.2% maximum				

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